UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,417	12/22/2004	Patrick Cornelis Nicolaas Rensen	101137-60	7547

27387 7590 07/31/2008

NORRIS, MCLAUGHLIN & MARCUS, P.A.
875 THIRD AVE
18TH FLOOR
NEW YORK, NY 10022

EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
07/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,417	RENSEN ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-20 and 22-33* is/are pending in the application.

4a) Of the above claim(s) *19,20,29 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,18,22-28 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment of April 16, 2008 has been entered. The examiner acknowledges the amendments to the specification. Claims 1-16 are cancelled. Claims 19-20 are withdrawn. Claims 17-18 and 22 are currently amended. Claims 27-33 are newly added.

Election/Restrictions

2. Newly submitted claims 29 and 33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The methods are distinct as claimed because they are drawn to independent and distinct processes having different functions and effects. For instance, claim 29 is drawn to an immune response produced by the presence of toxic components of bacteria, while claim 27 does not have that same limitation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 29 and 33 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 17-18, 22-28, and 30-32 are under consideration in this office action.

Withdrawal of Previous Rejections

4. The following objections and rejection are withdrawn in view of applicants' amendments and arguments:

a) The written description rejection of claims 12-18 and 22-26 under 35 U.S.C. 112, first paragraph;

b) The enablement rejection of claims 16-18 under 35 U.S.C. 112, first paragraph;

c) The rejection of claims 16-18 under 35 U.S.C. 112, second paragraph;

d) The rejection of claims 12-15 and 21-26 under 35 U.S.C. 102(b) as being anticipated by Quarfordt et al., J. of Biological Chem. 1982. Vol. 257(24): 14642-14647; and

e) The rejection of claims 12-15 and 21-26 under 35 U.S.C. 102(b) as being anticipated by Lauer et al., (J. Biol. Chem. 1988. Vol. 263(15): 7277-7286).

Claim Objections

5. Claim 32 is objected to because of the following informalities: Claim 32 depends upon itself. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 17-18, 22-28 and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The preamble of Claim 27 is unclear. Claim 27 is drawn to treating a mammal suffering from or is at increased risk of developing sepsis or septic shock. However it is unclear if the method is drawn to treating a mammal suffering from an increased risk of developing sepsis or septic shock, or if the method treats a mammal suffering from sepsis or septic shock. Therefore the metes and bounds of the preamble are unclear and clarification is required to overcome the rejection.

b) The phrase "at increased risk of developing sepsis or septic shock" in claim 27 is a relative term which renders the claim indefinite. The phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the phrase an unclear. What determines an increased risk and how will one of ordinary skill know when a mammal has an n increased risk as compared to other risks. Therefore clarification is required to overcome the rejection.

c) Claim 30 is drawn to the peptide comprising SEQ ID NO:2 and claim 31 is drawn to the peptide having the amino acid sequence of SEQ ID NO:2. It is unclear what the difference between the claims are. Since both claims recite “open” language; clarification is requested to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 18, 22, 23, 25, 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Quarfordt et al., J. of Biological Chem. 1982. Vol. 257(24): 14642-14647.

Claim 27 is drawn to a method for treating a mammal suffering from or is at increased risk of developing sepsis or septic shock comprising administering to such mammal a therapeutically effective amount of a peptide and pharmaceutically acceptably adjuvants where the peptide comprises the amino acid sequence SEQ ID NO.:11. Claim 28 is drawn to the peptide comprising SEQ ID NO: 1. Claim 18 is drawn to the mammal being at an increased risk of developing sepsis. Claim 22 is drawn to the peptide binding to lipoteichoic acids and wherein the composition is for preventing or treating a sepsis or septic shock in mammals. Claim 23 is drawn to the shock being caused by Gram-negative bacteria. Claim 25 is drawn to the shock being caused by the shock is caused by Gram-positive bacteria. Claims 30 and 31 are drawn to the peptide comprising SEQ ID NO:2.

Quarfordt et al., teach administering apo C apoproteins with pharmaceutically acceptable adjuvants to a mammal (page 14643, col.1). Quarfordt et al., teach purifying human apolipoprotein CI (apoCI) (page 14642, col.2). Quarfordt et al., teach

preparations of pharmaceutical compositions comprising triglyceride emulsions having ApoCI (page 14643, col.1). Quarfordt et al., teach administering the composition of ApoCI to rats. Table I shows the injected activity of ApoCI (page 14644, col.1). Quarfordt et al., teach the C apolipoproteins were active within emulsions supplemented with apolipoprotein E (page 14646, col. 1). Quarfordt et al., teach ApoCI having the sequences of claims 27-28.

Therefore Quarfordt et al., teach the instant claims.

Response to Arguments

8. Applicant's arguments filed April 16, 2008 have been fully considered but they are not persuasive. Applicants' argue that Quarfordt et al., do not teach administering compositions comprising apoC1 in a method for treating sepsis or septic shock.

In response to applicants' assertions, a well known process of administration f a well known composition does not become patentable upon the discovery of a new property for that same composition. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Furthermore, the inherent feature need not be recognized at the time of its use. There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.,* 355 F.3d 1313, 1320, 69USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described an enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348-49 (Fed. Cir. 1999) ("Because sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention.... An inherent structure, composition, or function is not necessarily known."). Therefore, because the administration of apoC1 having SEQ ID NO:1 and 11 was clearly taught in the prior art, it is irrelevant that the prior art did not recognize the key aspect of the apolipoproteins ability to treat sepsis or septic shock. Therefor applicants' argument is not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 17-18 and 22-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oosten et al., (J. of Biol. Chem. 2001. Vol. 276(23): 8820-8824) in view of Quarfordt et al., (J. of Biological Chem. 1982. Vol. 257(24): 14642-14647).

Claim 27 is drawn to a method for treating a mammal suffering from or is at increased risk of developing sepsis or septic shock comprising administering to such mammal a therapeutically effective amount of a peptide and pharmaceutically acceptably adjuvants where the peptide comprises the amino acid sequence SEQ ID NO.:11. Claim 28 is drawn to the peptide comprising SEQ ID NO: 1. Claim 17 is drawn to a method wherein the mammal is a human. Claim 18 is drawn to wherein the mammal is at increased risk of developing sepsis as a result of a surgical intervention or a weakened immune system. Claim 22 is drawn to the peptide binding to lipoteichoic acids and wherein the composition is for preventing or treating a sepsis or septic shock in mammals. Claim 23 is drawn to the shock being caused by Gram-negative bacteria. Claims 24, 26 and 32 are drawn to the mammal being a human, horse, cow, dog or cat. Claim 25 is drawn to the shock being caused by the shock is caused by Gram-positive bacteria.

Oosten et al., teach that apoE may be used therapeutically to protect against LPS-induced endotoxemia as known as sepsis (page 8820). Oosten et al., teach lipopolysaccarides (LPS) are a component of gram-negative bacteria which is the primary cause of gram-negative sepsis (page 8820, col. 1). Oosten et al., teach that all lipoproteins bind endotoxins and that combining lipoproteins with LPS before administration to mammals protects against endotoxin induced death (page 8820, col.2). Oosten et al., teach emulsion models for chylomicrons target LPS and prevent the further binding of LPS, thereby showing the importance of the lipoprotein-endotoxin interactions (page 8821, col.1). Oosten et al., teach administering emulsions having apoE to mammals (page 8821, col1). However Oosten et al, do not teach administering SEQ ID NO:11.

Quarfordt et al., teach administering to mammals emulsions comprising ApoE and ApoCI (page 14643, col.1). Table I shows the injected activity of ApoE and ApoCI (page 14644, col.1). Quarfordt et al., teach the C apolipoproteins were active within emulsions supplemented with apolipoprotein E (page 14646, col. 1).

Therefore it would have been prima facie obvious at the time of applicants' invention to apply the method for treating a mammal suffering from or is at increased risk of developing sepsis or septic shock comprising administering a therapeutically effectively amount of a peptide and pharmaceutically acceptably adjuvants where the apoC1 peptide as taught by Oosten et al., wherein the modification includes a peptide comprising SEQ ID NO:1 or 11 as taught by Quarfordt et al., in order to aide in liver perfusion and isolation of contaminated blood. One of ordinary skill in the art would

have a reasonable expectation of success by including ApoCI within the composition of method of treatment because the art teaches the administration of ApoC1 and ApoE together. Furthermore, ApoCI and ApoE are known to produced in emulsion chylomicron compositions; and Oosten et al., teach that emulsion chylomicron compositions target LPS and prevent the further binding of LPS. Furthermore, no more than routine skill would have been required to include the ApoCI with the emulsions comprising ApoE when Oosten et al., in view of Quarfordt et al., teach that combining the apolipoproteins before administration protects against endotoxin death.

Response to Arguments

10. Applicant's arguments have been fully considered but they are not persuasive. Applicants argue that one would not expect a beneficial effect of combining ApoE and ApoC. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would not need to assume anything because the art clearly teaches administering ApoC and ApoE together. One of ordinary skill in the art would have a

reasonable expectation of success by including ApoCI within the composition of method of treatment because the art teaches the administration of ApoC1 and ApoE together.

Furthermore, the well known process of administration a well known composition including ApoC and E, comprising SEQ ID NO1 and 11 does not become patentable upon the discovery of a new property for that same composition; i.e., the ability to treat sepsis or septic shock. As stated above, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. Therefore, no more than routine skill would have been required to administer the peptide composition when the prior art teaches that emulsion compositions target LPS; prevent the further binding of LPS and treat sepsis or septic shock.

Conclusion

11. No claims allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645